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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,324	04/08/2004	Bernard Ackerman	414877	8520

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EXAMINER	
HOLLOWAY, IAN KNOBEL	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,324	ACKERMAN ET AL.	
	Examiner	Art Unit	
	IAN K. HOLLOWAY	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(4/8/2004)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to application no. 10820324. This is the initial Office Action based on the 10820324 application filed 4/08/2004. Claims 1-9 and 18-20 as presented by applicant in the preliminary amendment are currently pending and considered below

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 6-7, 9, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by **Ackerman (US Pg Pub 2004/0225257)**.

Regarding **Claim 1, Ackerman** discloses: a single-lumen tubular body; **(11, Fig. 2,** the catheter**)** and an elongated balloon **(20,** an inflatable balloon**)** disposed distally on the single-lumen tubular body for insertion into a cervical canal of the uterus, the balloon sealed containing a fixed internal residual volume of fluid **(Paragraph 18,** the construction of the balloon**)** and having opposing portions which occlude both openings of the cervical canal when the fluid in the balloon is displaced to inflate the opposing balloon portions to prevent distal and proximal movement of the catheter independent of the length of the cervical canal.

Regarding **Claim 2, Ackerman** discloses: the single-lumen tubular body is flexible. **(Paragraph 16,** the catheter is flexible**)**.

Regarding **Claim 3, Ackerman** discloses: a fluid displacement sleeve **(13,** the semi-rigid sheath**)** slidably disposed over the single-lumen tubular body, the sleeve being moveable over the elongated balloon to displace the internal fluid from a proximal portion of the balloon to the opposing portions of the balloon which are adjacent the opposite openings of the cervical canal when the balloon is inserted therein, to inflate the opposing portions of the balloon.

Regarding **Claim 4, Ackerman** discloses: the fluid displacement sleeve is semi-rigid. **(13,** the semi-rigid sheath**)**

Regarding **Claim 6 and 7, Ackerman** discloses: the balloon is made from an elastomeric material and polyurethane. **(Paragraph 18,** an elastomeric material is preferred, for example polyurethane**)**.

Regarding **Claim 9, Ackerman** discloses: a surgical instrument insertion adapter assembly **(18,** the proximal end has an adaptor**)** disposed at a proximal end of the single- lumen tubular body.

Regarding **Claim 18, Ackerman** discloses: a single-lumen catheter; **(11, Fig. 2,** the catheter**)** and a surgical instrument insertion adapter **(18,** the proximal end has an adaptor**)** assembly disposed at a proximal end of the single-lumen catheter.

Regarding **Claim 19, Ackerman** discloses: the surgical instrument insertion adapter assembly includes a compressible sealing element **(18,** the device is used with

fluid exchange and must have a fluid tight seal**)** for creating a substantially fluid tight seal around a surgical instrument.

Regarding **Claim 20, Ackerman** discloses: the surgical instrument insertion adapter assembly includes a port **(18,** the port**)** for introducing a contrast medium into the uterine cavity via the single-lumen catheter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ackerman in view of **Cowan (US Patent 5947991)**.

Regarding **Claim 5, Ackerman** discloses the invention claimed as stated above except for the inflated portions of the balloon define a barbell-shape balloon structure when inflated in the cervical canal.

However, **Cowan** teaches the inflated portions of the balloon define a barbell-shape balloon structure when inflated in the cervical canal. **(43, Fig. 2,** the barbell shaped balloon**)**

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have a barbell shape as taught by **Cowan,** since **Cowan** states at column 1, lines 44-55 that such modification would hold the balloon in place. Thus, it would have been obvious to one of ordinary skill in the art to apply a barbell shape as taught in **Cowan**, to improve the balloon of **Ackerman** for the predictable result of making the device more effective.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ackerman in view of **Arnold et al. (US Pg Pub 2007/0078451)**.

Regarding **Claim 8, Ackerman** discloses the invention claimed as stated above except for a removable stylet for stiffening the single-lumen tubular body to facilitate insertion thereof in the cervical canal

However, **Arnold et al.** teaches a removable stylet **(6,** the stylet**)** for stiffening the single-lumen tubular body to facilitate insertion thereof in the cervical canal

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a guide wire as taught by **Arnold,** since **Arnold** states at paragraph 50 that such modification would make operation of the device possible for multiple locations. Thus, it would have been obvious to one of ordinary skill in the art to apply a stylet as taught in **Arnold**, to improve the catheter of **Ackerman** for the predictable result of making the device easier to use.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-9 and 19-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6511469. Although the conflicting claims are not identical, they are not patentably distinct from each other because only minor wording changes have been made, for example, the fluid displacement sleeve is referred to as an inflation sleeve.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ian K Holloway/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763